

REMARKS

Claims 1-49 are pending in the application with claims 22-35 currently under examination. Claims 1-21 and 36-49 have been withdrawn from consideration as being directed to a non-elected invention. Claims 22, 24 and 30 have been amended. Support for the amendment can be found throughout the application as filed. For example, support for the amendment to claims 22, 24 and 30 directed to providing an output to a user can be found at, for example, page 45, lines 2-5, and page 61, lines 20-26. Support for the amendment to claims 22, 24 and 30 directed to values for n parameters for measured biochemical components can be found at, for example, page 17, line 25 through page 18, line 19, and in the claims as originally filed. Accordingly, the amendments do not raise an issue of new matter and entry thereof is respectfully requested. Applicant has reviewed the rejections set forth in the pending Office Action, and respectfully traverse all grounds for the reasons that follow.

Rejections Under 35 U.S.C. § 101

Claims 22-35 stand rejected under 35 U.S.C. § 101 for being directed to non-statutory subject matter allegedly because they either lack a physical transformation outside a computer or lack a practical. The Office alleges that under the Interim Guidelines a method requires either a physical transformation or a concrete, tangible and useful result, or practical application. However, the claimed invention, directed to a method for assigning a cellular function to a component of a biochemical system neither presents the assigned cellular function in a tangible form nor produces a concrete, tangible and useful result. The Office further concludes that Applicant neither argues that the claims do recite a physical transformation of matter or a concrete, tangible and useful result.

Applicants respectfully point out that they have previously made of record that the Federal case law is clear that a physical transformation is not required to satisfy the statutory criteria of § 101. See, for example, Applicant's Response dated June 24, 2004, at pages 10-15. Applicants further respectfully point out that the record also is clear that the claimed invention recites a practical application or a concrete, tangible and useful as set forth in *State Street Bank & Trust Co. v. Signature Financial Group*, 149 F.3d 1368 (1998), 525 U.S. 1093 (1999) (cert. denied). See, for example, Applicant's Response cited above at pages 11-14. Applicants

respectfully request that the Office take note of these remarks of record. Further of note for the record, although the Office now refers to the Interim Guidelines published November 22, 2005, as the applicable authority over the M.P.E.P, Applicants respectfully point out that because the entire rationale and express language of, for example, M.P.E.P. § 2106 (IV)(B)(1) is referenced in and can be found set forth in Annexes II-V of the Interim Guidelines, all arguments of record with respect to the M.P.E.P remain applicable and are maintained and reasserted herein.

Applicants maintain that all of the above remarks of record both address the Office's comments in the current Office Action and show that the requirements of § 101 have been adequately satisfied.

Although clear from the claims as written, claims 22-35 recite that the determination of whether a multidimensional coordinate point is outside of a reference data element region and thereby assigned a cellular function is provided to a user. The output of providing the multidimensional coordinate point determination which assigns cellular function is a concrete, tangible and useful result.

While not conceding that the Interim Guidelines are the applicable standard compared to the Federal case law precedent, the claimed result nevertheless satisfies the Office's Guidelines. The claimed result is concrete because it satisfies the Office's "useful result" criteria since it has a specific, substantial and credible utility. The utility of the claimed invention is specific to the subject matter claimed, and not general, because the claims recite that the claimed determination of a multidimensional coordinate point outside of a reference data element region assigns a cellular function to a component of a biochemical network. Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, Nov. 22, 2005, section IV.B.2.b., *citing* M.P.E.P. § 2107 (*see also* Revised Interim Utility Guidelines Training Materials at page 5 (1999)). The utility is substantial because it has a real world use, namely, assigning cellular function to a biochemical component network, such as for diagnostic or therapeutic purposes. *Id.* The utility also is credible because there is no reason for one skilled in the art to question the objective truth of the statement of utility and it is currently available for use. *Id.* Therefore, the claimed invention produces a useful result under the non-binding Interim Guidelines because it yields a specific, substantial and credible result.

Second, the claimed invention also satisfies the Office's "tangible result" criteria because it yields an output to a user for the determination of a multidimensional coordinate point outside of a reference which thereby assigns cellular function to a component of a biochemical network. The Interim Guidelines correctly acknowledge that:

The tangible requirement does not necessarily mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing.

Interim Guidelines, Nov. 22, 2005, section IV.B.2.b(2) (emphasis added); *see also In re Lundgren* cited in Applicants' previous response.

Therefore, consistent with the Office's current acknowledgement, there is no requirement for a claimed invention to be either tied to a particular machine or to transform a thing to a different state. Accordingly, any rejection based on this requirement is respectfully requested to be withdrawn.

Under this "tangible result" prong of the Office's guidelines, the requirement for a tangible result also must be differentiated from three judicial exceptions to patentability, which are: (1) laws of nature; (2) physical phenomena, and (3) abstract ideas. The guidelines further define the meaning of "tangible" to be opposite of "abstract."

With respect to the first two judicial exceptions above, the invention claims neither a law of nature or a physical phenomena *per se*. Rather, the claimed invention is directed to methods for assigning cellular function to a component of a biochemical system. The methods include physically perturbing a component of a network, determining and comparing a multidimensional coordinate point representing a component of a perturbed biochemical system to a reference data element region and providing an output to a user of the determination wherein a multidimensional coordinate point outside of the reference is linked to and assigned a cellular function of the network. There is no recitation in this claim of merely a law of nature or a physical phenomena. Accordingly, the claimed invention cannot be statutory unpatentable under these two judicial exception.

Further, there also is nothing in the claimed invention that constitutes a mere abstract idea. First, the claimed invention is more than just an idea because it claims a method of for

assigning a cellular function to a component of a biochemical system from a biochemical system that is actually physically perturbed. The claimed method further determines whether a multidimensional coordinate point is within or outside a reference data element region to assign cellular function to a component of a biochemical network. Hence, the ability to assign cellular function to a component of a biochemical network is more than an idea. Rather, it is an actual outcome.

Second, the claimed invention also is not abstract. The term “abstract” is defined as:

[c]onsidered apart from any application to a particular object or specific instance insufficiently factual having no reference to a thing or things -- opposed to concrete. . . . Expressing a property, quality, attribute, or relation viewed apart from the other characteristics inhering in or constituting an object.

Webster's Third New International Dictionary, Unabridged. Merriam-Webster, 2002.

<http://unabridged.merriam-webster.com> (21 Aug. 2006) (emphasis added).

Applicants maintain that the claimed invention is sufficiently factual because it recites physically perturbing a component of a network, determining and comparing a multidimensional coordinate point for a component of the perturbed biochemical system to a reference and providing an output to a user where a multidimensional coordinate point outside of the reference is linked to and assigned a cellular function of the network. Further, the claimed invention is not claimed apart from, or without reference to a thing or to characteristics of an object because it specifically recites that the multidimensional coordinate point represents one or more components of a perturbed biochemical system. Accordingly, the invention is concrete and not abstract because it is sufficiently factual and does not recite purely theoretical ideas detached from a particular object. Therefore, the claimed invention also produces a tangible result under the non-binding Interim Guidelines because it does not claim a law of nature, a physical phenomena or merely abstract idea apart from any application to a particular object.

Finally, the claimed invention also satisfies the Office’s “concrete result” criteria. The Interim Guidelines define this prong as being the opposite of “concrete” which is “unrepeatable or unpredictable.” Interim Guidelines, Nov. 22, 2005, section IV.B.2.b(3). Applicants respectfully point out that the invention claims providing an output to a user of a comparison and that determines multidimensional coordinate points outside of references regions that result in

the assignment of cellular function to the biochemical network component. Further, the application provides detailed teachings and guidance throughout for how to make and use the invention by determining a multidimensional coordinate point for a physically perturbed component of biochemical network, comparing and determining multidimensional coordinate points outside of a reference data element region which assigns cellular function to the component, and providing the output to a user. Therefore, the claimed invention further produces a concrete result under the non-binding Interim Guidelines because it yields a result that predicts a property of a biochemical system.

In light of the above, Applicants maintain that claims 22-35 are directed to statutory patentable subject matter which has a practical application under the Federal case law precedent. Applicants further maintain that claims 22-35 also satisfy the Offices non-binding guidelines for statutory patentable subject matter for computer related inventions. Accordingly, withdrawal of this ground of rejection is respectfully requested.

Rejections Under 35 U.S.C. § 102

Claims 22-35 under 35 U.S.C. § 102(b) stand rejected as anticipated by Stoughton et al. allegedly because Stoughton et al. describe comparing microarray profiles that measure relative changes of mRNA and graded drug exposure. In particular, the Office maintains its contention that positional addressable transcript microarrays wherein measurements of graded drug exposure and levels of modification or perturbation describe a multidimensional coordinate point because the “microarrays inherently involve mRNA locations containing x and y dimensions (multidimensional coordinate points) for components of a physically perturbed system including n parameters (i.e. drug exposure and levels of perturbation).” Office Action at page 5, lines 2-4 and page 7, lines 17-20. Therefore, the Office fails to give patentable weight to Applicants’ showing that the invention claims a point containing n parameters whereas Stoughton merely describes single measurements obtained from microarrays.

When lack of novelty is based on a printed publication that is asserted to describe the same invention, a finding of anticipation requires that the publication describe all of the elements of the claims. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1349, 48 U.S.P.Q.2d 1225, (Fed. Cir. 1998) (quoting *Shearing v. Iolab Corp.*, 975 F.2d 1541, 1544-45, 24 U.S.P.Q.2d 1133, 1136

(Fed. Cir. 1992)). The Office has failed to meet this standard because the description in Stoughton et al. of microarray measurements and the assertion that x and y locations inherently describe a multidimensional coordinate is non-analogous and distinct from Applicants' claimed invention.

Applicants claim a multidimensional coordinate point including n parameters wherein n corresponds to the number of measured components within a biochemical or constituent system. Applicants have shown that none of the passages relied on by the Office support the contention that the cited art describes a multidimensional coordinate point as claimed. However, without addressing Applicants distinctions on the merits, the Office appears to dismiss all arguments by reiterating its previous remarks in essentially a verbatim manner. Compare, for example, the Office's initial ground of rejection reiterated at pages 4-6 in the current Office Action with the Office's response to Applicant's remarks at pages 6-8 in the current Office Action. Except for the intermingling of Applicants' remarks, the reasons for supporting its contention that Applicants response was unpersuasive were essentially identical to the initial reasoning. This apparent *pro forma* response suggests that very little, if any, consideration was given to Applicants' remarks and constitutes a waste of both Applicants' and the governments time and resources.

Applicants particularly pointed out in each of the cited passages why Stoughton et al. fail to describe a multidimensional coordinate point as claimed. However, none of these remarks were addressed on the merits. Regardless of the distinctions and Applicants analysis of the cited support in Stoughton et al., no reasons other than a cursory repeat of previous remarks why the above distinctions were unpersuasive has been provided.

For example, Applicants pointed out with particularity that the claimed multidimensional coordinate point refers to a coordinate or point corresponding to the number of measured components of a biochemical system. Applicants distinguished the passage at column 45, lines 17-39, because it is directed to the production of arrays or microarrays where analytes are produced at different locations within the array. Different locations within an array does not describe a multidimensional coordinate point as claimed because locations in an array are non-

analogous to, and do not correspond to, parameters of measured components included in a multidimensional coordinate point.

Applicants distinguished the passage at column 46, lines 58-67, also because it is directed to microarrays describing placement of an analyte at known locations in an array. Placement of analytes at particular locations in an array does not describe, and is non-analogous to, the claimed multidimensional coordinate point.

The passage at column 51, lines 39-49, also was distinguished and shown not to describe the claimed multidimensional coordinate point because this passage describes the hybridization of a mixture of labeled probes to a microarray. Such a description fails to describe the claimed multidimensional coordinate point. With reference to this hybridization assay, Stoughton et al. describe:

In order to perform experiments according to this invention . . . cDNAs (or mRNAs) are derived from the two cells and differently labeled according to the cell of origin, and are used to construct transcript arrays, which are measured to find the mRNAs with modified expression and the degree of modification due to exposure to the drug.

Column 51, lines 50-63 (emphasis added).

Describing that the hybridization of probes to a microarray for the purpose of determining which mRNAs are modified in response to a drug is non-analogous to, and fails to describe a point defined by n parameters in multidimensional space because Stoughton's assay is a comparison of single measurements obtained under one condition compared to measurements obtained under a different condition.

Applicants further distinguished the passage at column 52, lines 1-17, because it is directed to the amount and quality of individual gene response measurements. In particular, this passage describes the density of individual gene responses. A description of density of gene responses is non-analogous and distinct from Applicants claimed multidimensional coordinate point.

The Office relies on the alleged inherency of the microarrays describing a multidimensional coordinate point, reasoning that "microarrays inherently involve mRNA

locations containing x and y dimensions (multidimensional coordinate points).” Office Action, *supra* (emphasis added). Applicants fail to discern how an x / y coordinate of a location within a microarray describes a multidimensional coordinate point representing values of n measured components. The x and y dimensions correspond to a location, not a multidimensional coordinate point. It therefore describes a position of a single component and is not multidimensional, failing to represent n parameters for n measured biochemical components. Accordingly, a location is non-analogous and distinct from the claimed multidimensional coordinate point

Although believed to be clear as written, Applicants have amended the claims to expressly recite that the claimed multidimensional coordinate point includes values for n parameters which corresponds to the number of measured biochemical components. A point having multiple values for measured biochemical components clearly is not described by the descriptions in Stoughton et al. to microarrays, hybridization measurements or locations within a microarray. Accordingly, this ground of rejection is moot and its withdrawal is respectfully requested.

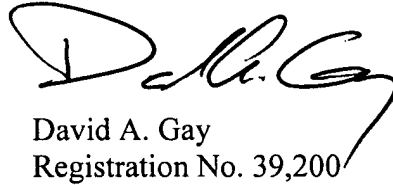
CONCLUSION

In light of the Remarks herein, Applicants submit that the claims are in condition for allowance and respectfully request a notice to this effect. Should the Examiner have any questions, she is invited to call the undersigned attorney.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read 'D. A. Gay', written over the printed name and registration number.

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